1.0 Purpose:

To establish a framework for the identification and review of adverse drug reactions (ADRs), thereby to;

1.1 Inform healthcare providers about ADRs to improve patient care

1.2 Identify trends to prevent future ADRs

1.3 Define the role of medical, nursing, pharmacy, and other healthcare personnel in ADR reporting to insure multidisciplinary participation

1.4 Report and evaluate ADRs occurring in the organization

2.0 DEFINITION:

2.1 An ADR is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding therapeutic failure

2.2 ADRs are to be reported if they result in any of the following

2.2.1 Hospital admission

2.2.2 Adjustment or discontinuation of drug therapy

2.2.3 Requirement of systemic treatment

2.2.4 Prolongation of hospital stay

2.2.5 Complication of diagnosed disease state

2.2.6 Patient death

3.0 PROCEDURE:

3.1 Orientation for all medical, nursing staff and pharmacists describing the importance of ADR reporting and the role of the healthcare provider in the ADR reporting program

3.2 Adverse drug reactions meeting at least one of the criteria stated in definition shall be reported by raising an incident report within 24 hours from the time of occurrence.

3.3 Medical / nursing / pharmacist shall be responsible for reporting suspected ADRs that meet the above definition and reporting criteria. ADRs are reported by completing the Patient Incident Report form.

3.4 The patient's primary physician shall be responsible for confirming or ruling out any suspected adverse reaction reported to them or identified by them.

3.5 The patient's primary physician shall document the reaction in the patient's medical record when an adverse drug reaction has been confirmed.

3.6 All reported ADRs shall be reviewed monthly by the Drug & Therapeutics committee

3.7 A summary *of* reported ADRs shall be forwarded to the Quality Team on a Monthly basis.

5.0 Responsibilities:

5.1 Drug Committee members

5.2 All physicians

6.0 Applicability: Medical, Nursing and Pharmacy personnel